

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-350V

June 18, 2007

MADELINE WILK,

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Petitioner,

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v.

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Hepatitis B vaccination followed

11 days later by optic neuritis

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SECRETARY OF THE DEPARTMENT OF

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HEALTH AND HUMAN SERVICES,

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Respondent.

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ORDER TO SHOW CAUSE¹

Petitioner filed a petition dated February 14, 2003, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on October 8, 2000 caused her optic neuritis, a demyelinating disease. Petitioner in her affidavit states that this hepatitis B vaccine was administered on September 26, 2000. Med. recs. at Ex. 1.

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

The medical records show that the onset of her optic neuritis was October 7, 2000, 11 days after her third hepatitis B vaccination, when she had diminished vision in the lower field of her right eye. Although initial examinations of petitioner showed nothing abnormal on MRI, she was ultimately diagnosed with optic neuritis.

Respondent is ORDERED TO SHOW CAUSE by **August 31, 2007** why this case should not proceed to damages.

FACTS

Petitioner was born on November 11, 1948.

On February 21, 2000, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 10, p. 3.

On March 21, 2000, petitioner received her second hepatitis B vaccination. *Id.*

On September 26, 2000, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 10, p. 4.

On October 11, 2000, petitioner saw Dr. Leon A. Bynoe, a specialist in the retina and vitreous. Med. recs. at Ex. 11, p. 12. Petitioner noticed an inferior field defect in her right eye for the last four days. She denied any ocular pain, flashers, or floaters. *Id.* Dr. Bynoe's impression was optic neuropathy of the right eye, possible sectoral anterior ischemic right eye, and lattice degeneration of the left eye. He strongly suspected it was an ischemic optic neuropathy which involved only a small segment of the optic nerve head. Med. recs. at Ex. 11, p. 13.

On October 24, 2000, petitioner saw Dr. Gary Hopen, stating her inferior visual field was in shadow on October 7, 2000. She saw her optometrist, Mark Goldberg. Med. recs. at Ex. 11, p. 3. There was no definite change since. *Id.*

On October 25, 2000, Dr. Hopen wrote a letter to Dr. Leon A, Bynoe. Med. recs. at Ex. 10, p. 9. Petitioner had a swollen right optic nerve that could represent either an anterior ischemic optic neuropathy or papillitis from optic neuritis. Med. recs. at Ex. 10, p. 10. Dr. Hopen could not distinguish between the two diagnoses in petitioner. *Id.*

On October 25, 2000, petitioner had an MRI of the brain and orbits with and without gadolinium. Med. recs. at Ex. 11, p. 6. The MRI was unremarkable. *Id.*

On October 31, 2000, petitioner saw Dr. Daniel Kan, a neurologist. Med. recs. at Ex. 10, p. 6. On October 7, 2000, petitioner developed a shadow of the right lower field which had been constant and getting worse. An MRI of her brain with gadolinium was unremarkable. *Id.*

On November 10, 2000, petitioner had an MRA (magnetic resonance angiography) of the brain. Med. recs. at Ex. 11, p. 26. Dr. Joseph Kozlowski's impression was marked decreased identifiable flow in the A1 segment of the right anterior cerebral artery. That could represent normal variant hypoplasia or a marked stenosis. *Id.* Otherwise, the MRA was unremarkable. Med. recs. at Ex. 11, p. 27.

On November 15, 2000, petitioner saw Dr. Joel S. Glaser, a neuro-ophthalmologist, telling him that she woke on the morning of October 7, 2000 with a sensation of diminished vision in the lower field of her right eye. She saw Dr. Gary Hopen on October 24, 2000, who recorded right eye vision of 20/25 +2, with an inferior altitudinal field defect and afferent pupil. Med. recs. at Ex. 9, p. 64. A neurologist saw her but made no specific neurologic findings. She

was otherwise well. *Id.* The MRI showed no defects, but there was no FLAIR sequence for white matter disease. Med. recs. at Ex. 9, p. 65.

On April 11, 2001, petitioner had another MRA of her brain done. Med. recs. at Ex. 11, p. 9. Dr. Joseph Kozlowski's impression was that there was a lack of identifiable flow in the A1 segment of the right anterior cerebral artery, most compatible with hypoplasia (normal variant). Otherwise, it was an unremarkable MRA of the circle of Willis and vertebrobasilar system. *Id.*

Also on April 11, 2001, petitioner had another brain MRI done with and without contrast. Med. recs. at Ex. 13, p. 6. Dr. Joseph Kozlowski's impression was mild nonspecific bilateral white matter disease. Med. recs. at Ex. 13, p. 7. An additional FLAIR sagittal sequence was performed. Med. recs. at Ex. 13, p. 6. There were scattered foci of hyperintense T2 and FLAIR signal in the white matter bilaterally, involving the periventricular, deep, and subcortical white matter. These white matter lesions were indeterminate. The differential diagnosis included MS, a vasculitis, and mild chronic small vessel ischemic disease. *Id.* Petitioner also had a mildly asymmetric enhancement in the left cerebral hemisphere, most likely representative of a normal variant of a prominent blood vessel or venous angioma. Med. recs. at Ex. 13, p. 7.

On March 12, 2002, April 15, 2002, and August 14, 2003, Dr. Joel Glaser wrote notes that petitioner had bilateral optic neuritis. Med. recs. at Ex. 9, pp. 6, 7, and 21.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen

v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said “we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...”

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had optic neuritis, but also that the vaccine was a substantial factor in bringing about her optic neuritis. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Optic neuritis is not one of the demyelinating illnesses making up the four paradigmatic cases discussed in the Omnibus proceeding on hepatitis B vaccine and demyelinating disease. However, it is not unusual for the onset of multiple sclerosis (MS) to include optic neuritis. Petitioner does not have MS, but she does appear to have a demyelinating illness whose onset was 11 days post-hepatitis B vaccination. Although there was some question of a vascular cause

of her visual problems, her neuro-ophthalmologist Dr. Joel Glaser diagnosed her eventually with bilateral optic neuritis.

In Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks. *Id.* at *18.

Respondent is ORDERED TO SHOW CAUSE why this case should not proceed to damages by **August 31, 2007**.

IT IS SO ORDERED.

June 18, 2007
DATE

s/Laura D. Millman
Laura D. Millman
Special Master